THIS OPINION WAS NOT WRITTEN FOR PUBLICATION
This decision is not binding precedent of the Board.

Paper No. 43

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte VIC C. KNAUF
and GREGORY A. THOMPSON

Appeal No. 96-0051
Application No. 07/987,256[1]

HEARD: 9 April 1999

Before WINTERS, JOHN D. SMITH, and TORCZON, Administrative Patent Judges.

TORCZON, Administrative Patent Judge.

DECISION ON APPEAL

Appellants seek review under 35 U.S.C. § 134 from the final rejection of claims 21, 25, 27, 33, 34, 37, 40, 41, and 51-60, all of the then-pending claims. Appellants subsequently amended several claims, canceled claims 56-60, and added claims 61 and 62 (Paper 33 (Amdt. filed 7 Nov. 1994)). Existing rejections were extended to new claims 61 and 62. We affirm the rejection of claims 21, 25, 27, 33, 34, 37, 40, 54, and 55, but reverse the rejection of claims 41, 51-53, 61, and 62.

[1] Attorney docket no. CGNE 76.

BACKGROUND

Appellants disclose the manipulation of plant fatty-acid content by altering fatty-acid synthase activity. Claims 21 and 37 (reproduced below) are representative of the claimed subject matter.

> 21. A cDNA sequence encoding a *Ricinus communis* $-ketoacyl-ACP synthase protein, wherein said cDNA sequence comprises the mature protein encoding portion of said synthase protein, and wherein said mature protein has a molecular weight of approximately 50 kD.

(Paper No. 20 (Amdt. filed 10 Aug. 1993) at 1.)

> 37. A DNA construct comprising, in the 5' to 3' direction of transcription, a transcription initiation region functional in a plant seed cell, said $-ketoacyl-ACP synthase protein encoding sequence of Claim 21 or Claim 25[2] and a transcriptional termination region functional in a plant seed cell, wherein said $-ketoacyl-ACP synthase protein encoding sequence is oriented for expression of antisense sequence.

(Paper No. 33 at 2.)

In the examiner's answer (Paper No. 37), the following rejections remain:

1. An obviousness-type double-patenting rejection of claims 21, 25, 27, 33, 34, 37, 40, 54, and 55 in view of the claims of Appellants' 07/721,761 application (now United States Patent 5,475,099);

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[2] Claim 25 is identical to claim 21 except that the molecular weight specified is 46 kD instead of 50 kD (Paper No. 20 at 1-2).

2. A written description and enablement rejection under 35 U.S.C. § 112[1] of claims 37 and 40; and

3. An enablement rejection under section 112[1] of claims 21, 27, 33, 34, 37, 40, 41, 51-55, 61, and 62.

DISCUSSION

Obviousness-type double-patenting

At the hearing, in response to a direct question from the bench on the matter, counsel for Appellants stated that they are no longer contesting the double-patenting rejection. Counsel further indicated that an appropriate terminal disclaimer would be submitted when the application is returned to the examiner. In light of this concession, the obviousness-type double-patenting rejection of claims 21, 25, 27, 33, 34, 37, 40, 54, and 55[3] in view of the claims of Appellants' 07/721,761 application (now United States Patent 5,475,099) must be affirmed.

Support for the antisense claims

The examiner has rejected claims 37 and 40 for lacking both written description and enabling description in the specification. The written description requirement and the enablement requirements are separate requirements. E.g., In re Wilder, 736 F.2d 1516, 1520,

[3] It is not clear from the record why claims 41, 51-53, 61, and 62 were not also subject to this rejection. Since a terminal disclaimer will encompass all of the claims in the resulting patent, however, the question is moot on this record.

222 USPQ 369, 372 (Fed. Cir. 1984); Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116-17 (Fed. Cir. 1991). To satisfy the written description requirement, the specification must clearly convey to those skilled in the art the information that the Applicant invented the claimed subject matter. Vas-Cath, Inc., 935 F.2d at 1562, 19 USPQ2d at 1115. A lack of enablement rejection is appropriate where the written description fails to teach those in the art to make and use the invention as broadly as it is claimed without undue experimentation. In re Cortright, 165 F.3d 1353, 1356, 49 USPQ2d 1464, 1466 (Fed. Cir. 1999).

According to the examiner, claim 37 would require undue experimentation because

> there is no guidance as to what segments to invert or what promoter to use in order to alter transcription and avoid deleterious effects of altering expression of fundamental biochemical processes.

(Paper No. 37 at 5.) Moreover, the examiner urges that the relationship of the 46 kD protein and any of the 50 kD proteins to synthases I and II is not clearly established in the specification.

The specification describes the construction of synthase expression cassettes (Paper No. 1 at 95-100). Antisense constructs can use the same expression cassettes (Paper No. 1 at 102). Claim 37 requires the inversion of the "sequence of Claim 21 or Claim 25" so, to the extent claims 21 and 25 are definite and supported, there

should be no question of what segments to invert: the entire sequence must be inverted. On this record, there is ample guidance for how to prepare a synthase antisense cassette. Although more detail in the specification might have been better, it is not required. See Northern Telecom, Inc. v. Datapoint Corp., 908 F.2d 931, 941, 15 USPQ2d 1321, 1329 (Fed. Cir. 1990) (A production specification is not required for enablement).

As far as the relationship of the proteins described in claims 21 and 25 to synthases I and II is concerned, neither claim requires any specific relationship. Each only claims a protein with an approximate molecular weight that is a *Ricinus communis* $-ketoacyl-ACP synthase protein, but does not specify type I or type II. Claim 37 requires no more. Thus, any questions about the relationship of the proteins in the claims to the synthases of the specification is moot.

Similarly, the examiner's concern about whether the antisense would work, i.e., would decrease the effects of the synthase, is misdirected. Claim 37 is directed to a DNA construct, not a method of reducing synthase activity. Moreover, the construct need only permit the expression of the encoding sequence in an antisense orientation. Whether or not the expression product reduces synthase activity is not relevant to understanding the claimed subject matter.

On the record before us, the examiner has not carried her burden of demonstrating undue experimentation.

The examiner gives no specific rationale for the written description rejection. We note that the specification lists "nucleic acid constructs...designed to decrease expression of endogenous synthase...[using] an anti-sense synthase under the control of a promotor" as part of the invention (Paper No. 1 at 9; see also Paper No. 1 at 13 and 17). Absent a clearer statement of the rejection, a preponderance of the evidence of record supports a finding of adequate written description.

Enabling support for the 50 kD claims

The claim with the 50 kD protein element, claim 21, and claims depending from it stand rejected as not enabled because it is not clear which 50 kD protein is characterized by the disclosed amino-acid and encoding polynucleotide sequences (Paper No. 37 at 6). The examiner notes that several 50 kD proteins are mentioned in the specification, including a protein contaminant, a protein related to synthase I activity, and a protein related to synthase II activity (Paper No. 37 at 11).

Claim 21 does not refer to the protein contaminant. The point of the ACP-Sepharose column was to isolate proteins with synthase activity. ACP (acyl carrier protein) is part of the substrate for

$-ketoacyl-ACP synthase proteins (Paper No. 1 at 8). A person skilled in the art, upon reading in the specification that

> The ACP column removes several proteins including a major contaminant which also showed a molecular weight at about 50 kD[]

would have understood that the contaminant was so designated because it lacked synthase activity. Consequently, the examiner's concern about the 50 kD contaminant is not supported by the preponderance of evidence of record.

Appellants contend that there is only one disclosed 50 kD protein with synthase activity (Paper No. 30 (App. Br.) at 15). According to the specification, a 50 kD synthase protein elutes in two fractions. The first fraction primarily has synthase II activity; the second, primarily synthase I activity. The specification indicates that two-dimensional gel analysis of the 50 kD protein band with synthase II activity produces "at least two spots" (Paper No. 1 at 23-24). The specification does not explain these two spots. It continues by explaining that the 50 kD proteins with synthase I and synthase II activities appear to be closely related (Paper No. 1 at 24). From that point on, the specification refers to "the 50 kD protein" as though only one 50 kD protein is relevant.

Claim 21 requires an enabling disclosure for a cDNA encoding a 50 kD *Ricinus communis* $-ketoacyl-ACP synthase protein. The

specification provides guidance on how to isolate a cDNA for at least one such protein (Paper No. 1 at 24-25). The enablement rejection is thus best understood as a scope of enablement rejection. See Cortright, 165 F.3d at 1356, 49 USPQ2d at 1466 (characterizing enablement scope rejections). The question is whether one skilled in the art at the time of filing could have isolated a cDNA for each 50 kD synthase protein. Assuming, arguendo, that the specification discloses two 50 kD synthase proteins, it explains how to isolate both proteins (Paper No. 1 at 24) and how to generate probes for a *R. communis* cDNA library based on partial sequences of the isolated protein (Paper No. 1 at 24-25). The examiner has not explained why this would not be sufficient. Although the examiner notes the confusion regarding the identity and relationship of the disclosed proteins, the rejection before us is lack of enablement, not written description.[4] As previously noted, these are distinct requirements with distinct tests. Consequently, we do not find a preponderance of evidence in the record to support the enablement rejection of claim 21.

Objections to the specification

[4] Since the filing of the present appeal, the Court of Appeals has clarified the application of the written description requirement in biotechnology sequence cases. Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1405 (Fed. Cir. 1997).

Objections to the specification are not reviewed on appeal. See Manual of Patent Examining Procedure § 706.1.

DECISION

The obviousness-type double-patenting rejection of claims 21, 25, 27, 33, 34, 37, 40, 54, and 55 in view of the claims of Appellants' 07/721,761 application (now United States Patent 5,475,099) is affirmed. The written description and enablement rejection under 35 U.S.C. § 112[1] of claims 37 and 40 is reversed. The enablement rejection under section 112[1] of claims 21, 27, 33, 34, 37, 40, 41, 51-55, 61, and 62 is reversed.

The period for taking any subsequent action in connection with this appeal will be extended only under the limited circumstances provided in 37 CFR § 1.136(b).

AFFIRMED-IN-PART

SHERMAN D. WINTERS
Administrative Patent Judge

JOHN D. SMITH
Administrative Patent Judge

RICHARD TORCZON
Administrative Patent Judge

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